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09/812,704	03/19/2001	Charles Lewis	01-P-24995	9722

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EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/812,704

Applicant(s)

LEWIS ET AL.

Examiner

Luke Gilligan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37, 39-46 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37, 39-46, and 51-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. In the amendment filed 10/30/06, the following has occurred: claims 1, 13, 25, 37, and 46 have been amended. Now, claims 1-37, 39-46, and 51-56 are presented for examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-37, 39-46, and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snail, **The Effects of Hospital Contracting for Physician Services on Hospital Performance** in view of Leet, U.S. Patent No. 6,000,828.
4. As per claim 1, Snail discloses a method of managing a healthcare practice participating in an insurance network to enhance profitability of the healthcare practice with respect to a predetermined reimbursement amount for pharmacy costs, the method comprising: gathering data for each of a plurality of physicians in the healthcare practice participating in the insurance network regarding management of the pharmacy costs other than those attributed by a medical procedure performed directly by each of the plurality of physicians when the physician directly administers a medication to a patient to thereby define ancillary pharmacy costs (see page 156, in particular, the statistical profiles used to compare physician practices); identifying at least one of the plurality of physicians in the healthcare practice participating in the insurance network that is at a greater risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network by prescribing medications that are detrimental to receiving the predetermined reimbursement amount for the ancillary pharmacy

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costs (see pages 156 and 161, in addition to identifying physicians by comparing individuals to other peer physicians, it is noted that incentive payments are disclosed as being based on costs, therefore, identified physicians would at least be at risk of not receiving the potential full amount of incentive payments identified in Snail); and after the step of identifying, modifying management behavior of the at least one of the plurality of physicians at the greater risk regarding the ancillary pharmacy costs to substantially reduce the risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network and thereby increase the profitability of the healthcare practice (see pages 162-163, it is noted that education is one of the disclosed methods of modification of physician behavior).

5. Snail does not explicitly disclose a tangible computer medium for gathering the data regarding the physicians. However, gathering data in a tangible computer medium is old and well known in the art as taught by Leet in which data regarding medical cost information is gathered in a tangible computer medium (see column 15, lines 11-28). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a computer tangible medium into the system of Snail. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of reducing the amount of paper records needed in Snail by automating the data collection process. In addition, such automation of such a process would aid in overcoming the difficulty in monitoring physician practice identified in Snail (see page 162).

6. As per claim 2, Snail in view of Leet discloses the method of claim 1 as described above. Snail does not explicitly teach that the ancillary pharmacy costs are gathered from a database associated with a pharmacy network, positioned on a server. Leet teaches gathering data regarding pharmacy costs from a database associated with a pharmacy network, the database positioned on a server (see column 18, line 49 – column 19, line 13 and column 5, line 65 –

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column 6, line 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the method of Snail for the reasons given above with respect to claim 1.

7. As per claim 3, Snail in view of Leet disclose the method of claim 1 as described above. Snail further discloses analyzing the ancillary pharmacy costs of each of the plurality of physicians in the healthcare practice to compare statistical profiles of physicians to one another (see page 156). However, Snail does not explicitly disclose calculating an average ancillary pharmacy cost per physician for the healthcare practice, and identifying the physicians that have ancillary pharmacy costs that are a predetermined percentage greater than the average ancillary pharmacy costs per physician for the healthcare practice. However, the Examiner takes Official Notice that it is old and well known in the art of statistical profiling to calculate averages and identify entities that are a predetermined percentage greater than the average. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a statistical analysis into the combined teachings of Snail and Leet. One of ordinary skill in the art would have been motivated to incorporate such a teaching for the purpose of evaluating performance to structure managed care contracts (see page 156 of Snail).

8. As per claim 4, Snail in view of Leet discloses the method of claim 1 as described above. Snail further discloses selecting the physician having the highest ancillary pharmacy costs within the healthcare practice (see page 156).

9. As per claim 5, Snail in view of Leet discloses the method of claim 1 as described above. Snail further discloses modifying physician behavior through education (see page 163). However, Snail does not explicitly disclose modifying by educating the at least one physician on the benefits of alternative prescription medications using research literature for comparing the

alternative medications to the prescribed medication and organizing continued medical education classes to educate each of the plurality of physicians in the healthcare practice on the benefits of the alternative prescription medications. However, Leet teaches such education by providing information regarding alternative prescription medications that can be ranked both by effectiveness and by cost (see column 14, lines 8-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the method of Snail. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of providing enhanced services to physicians based on the constantly evolving nature of medical knowledge (see column 11, lines 48-51 of Leet).

10. As per claim 6, Snail in view of Leet discloses the method of claim 5 as described above. Although Snail describes treatment-based guidelines for receiving the reimbursement amount, the reference does not explicitly teach preparing a list of prescription medications that the at least one physician may prescribe that enable the physician to receive the predetermined reimbursement amount for the ancillary pharmacy costs. However, Leet teaches presenting a list of prescription medications to physicians that the physician may prescribe based in part on cost (see column 14, lines 19-30) for the purpose of reducing healthcare costs (see column 1, lines 5-11). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the method of Snail. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of reducing healthcare costs without sacrificing the quality of health care provided to patients (see column 1, lines 5-11 of Leet).

11. As per claim 7, Snail in view of Leet disclose the method of claim 6 as described above. As described above, Snail does not explicitly disclose providing the alternative medications. However, Leet further teaches providing customer prescription medication forms that include the

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list of prescription medications that the at least one physician may prescribe (see Table III). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Snail for the reasons given above with respect to claim 6.

12. As per claim 8, Snail in view of Leet disclose the method of claim 7 as described above. Snail further discloses modifying physician behavior by utilizing payment incentive mechanisms based on the use of treatment protocols (see page 162 and Table A2.3). Snail does not explicitly disclose preparing a list of common prescription medications that are approved by each of the plurality of insurance networks so as to enable the at least one physician to receive the predetermined reimbursement amount for the ancillary pharmacy costs. However, Leet teaches preparing a list of suggested medications and corresponding costs (see column 25-29 and Table III). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize such a list as taught by Leet in conjunction with the use of treatment protocols. One of ordinary skill in the art would have been motivated to utilize such a list for the purpose of aiding in reducing unnecessary or inappropriate utilization (see page 162 of Snail).

13. As per claim 9, Snail in view of Leet disclose the method of claim 7 as described above. Snail does not explicitly teach analyzing the patient's prescription history to thereby avoid possible adverse prescription medication reactions. However, Leet teaches analyzing the patient's prescription history to thereby avoid possible adverse prescription medication reactions (see column 18, lines 57-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Snail for the reasons given above with respect to claim 6.

14. As per claim 10, Snail in view of Leet disclose the method of claim 9 as described above. Snail further discloses utilizing payment incentive mechanisms based on a review of the

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appropriateness of treatment prescribed by physicians (see page 162 and Table A2.3).

However, Snail does not explicitly disclose discontinuing the at least one patient's present prescription medications based on the review. Leet teaches discontinuing at least one patient's present prescription medications that have inadequate clinical effect (see column 19, lines 30-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate such a feature into the system of Snail for the reasons given above with respect to claim 6.

15. As per claim 11, Snail in view of Leet disclose the method of claim 10 as described above. As noted above, Snail does not explicitly teach discontinuing the patients present medication, however, this is old and well known as evidenced by Leet above incorporated herein. In addition, neither Snail nor Leet explicitly teach the use of a physician's letterhead for communicating notification of discontinuing a prescription medication. The Examiner takes Official Notice that physician's letterhead used for physician communications such as discontinuing medications is old and well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the use of physician's letterhead into the combined teachings of Snail and Leet. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of providing a professional means for communication with patients and pharmacies.

16. As per claim 12, Snail in view of Leet disclose the method of claim 1 as described above. Snail further discloses updating each of the plurality of physicians in the healthcare practice of any changes in the management of ancillary pharmacy costs from the insurance network (see page 156, in particular, physician profiles that are compared to practice guidelines are disseminated to physicians).

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17. Claims 13-23 recite substantially similar limitations to those already addressed in claims 1-12 and, as such, are rejected for similar reasons as given above.

18. As per claim 24, Snail in view of Leet teach the method of claim 20 as described above. Snail further teaches the ancillary medical costs include any costs taken from the listed group (see pages 156 and 161).

19. Claim 25 recites substantially similar limitations to claim 13 with the additional limitation of providing a financial incentive to the insurance network and the plurality of physicians in the healthcare practice participating in the insurance network to modify the plurality of physicians' management behavior of ancillary medical costs that are not as profitable to the insurance network which is also taught by Snail (see pages 156 and 161). Claims 26-36 recite substantially similar additional limitations to those already addressed in claims 12-24 and, as such, are rejected for similar reasons as given above.

20. Claims 37, 39-46, and 51-56 recite substantially similar system limitations to those already addressed in method claims 12-24 and, as such, are rejected for similar reasons as given above.

Response to Arguments

21. In the remarks filed 10/30/06, Applicants argue in substance that (1) Snail and Leet fail to recognize the problem or source of the problem of the invention; (2) there is no motivation to combine Snail and Leet; (3) Snail and Leet are non-analogous references; (4) Snail and Leet does not suggest the desirability of the combination; (5) neither Snail nor Leet are directed to measuring or controlling costs and cost-effectiveness of care; (6) Snail does not teach that ancillary medical costs are or should be a driving incentive factor; (7) Snail is a non-enabling disclosure; (8) the term "education" is not any sort of payment mechanism and is not applied to

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ancillary costs; (9) Leet does not teach gathering data regarding physicians in a healthcare group in a tangible computer medium; (10) Snail and Leet fail to teach limitations of the dependent claims.

22. In response to Applicants' argument (1), although it is alleged that Snail and Leet "fail to recognize the problem or source of the problem," the Examiner was unable to identify any particular remarks that identify the "source of the problem" and how Snail and Leet have failed to recognize it. Rather, it appears that Applicants' have alleged that the source of the problem is, essentially, method steps recited in some of the independent claims. Furthermore, it should be noted that the portion of the MPEP relied on by Applicants' indicate that the identification of the source of the problem may be the patentable invention "even though the remedy may be obvious once the source of the problem is identified" *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969) (emphasis added). It is unclear, since there is no further discussion, whether Applicants' are acknowledging that the steps and elements "to solve the problem" are obvious, while the discover of the "source of the problem" is not. Therefore, the Examiner requests further clarification on this matter.

23. In response to Applicants' argument (2) the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner has clearly provided motivation that is supported both by the references themselves as well as the knowledge generally available to one of ordinary skill in the art at the time of the invention (see, for example, paragraph 5 above). Despite Applicants' general allegation that the Examiner has

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failed to provide motivation, there did not appear to be any discussion the remarks directed to this clear and unambiguous discussion provided in the previous office action.

24. In response to Applicants' argument (3), it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it appears that Applicants' have chosen certain aspects of Leet to support this contention, while ignoring the teachings of Leet, as a whole, and, more importantly, the teachings relied upon in the rejections above. The Examiner respectfully maintains that the applied prior art references are analogous art and submits that they are both generally related to gathering hospital data for analysis. Furthermore, with respect to Applicants' assertion that neither reference is directed to "outpatient care or open healthcare systems," it should be noted that the claims make no mention of "outpatient care or open healthcare systems." Therefore, the Examiner does not find this argument to be persuasive.

25. In response to Applicants' argument (4), Applicants are reminded that "a suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art, as the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. . . . The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). In this case, the Examiner respectfully maintains, for reasons given above, that the motivation to combine the references has been clearly articulated and supported by the references themselves, along with a reasonable rationale.

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26. In response to Applicants' argument (5), the Examiner respectfully disagrees that the claims are necessarily directed to measuring costs. Rather, the claims are directed to gathering data "regarding management of" costs. Therefore, it is important to note that the data that is "measured" (i.e. gathered) is data regarding management of costs specific cost data itself. In other words, the claims never require any measurements of costs to be taken. Nevertheless, the Examiner finds this argument to be curious since the entire dissertation of Snail is directed to controlling hospital costs through contracting with physician practices (see abstract).

27. In response to Applicants' argument (6), it is unclear to the Examiner what not being a "driving incentive factor" has to do with determining whether the reference teaches using ancillary medical costs as a form of incentive payment. It appears that Applicants' are asserting that because the ancillary costs are not a driving factor, they are not an incentive payment. The Examiner respectfully disagrees and submits that this portion of Snail cannot simply be ignored because of this. It should also be noted that the claims make no mention whatsoever of what portion of overall compensation the incentive payments make. Therefore, the Examiner does not find this argument to be persuasive.

28. In response to Applicants' argument (7), despite the general allegation that the reference is not enabled, it is noted that Applicants' have not identified a particular teaching that the Examiner has used that is not enabled, when considered along with the knowledge generally available to one of ordinary skill in the art at the time of the invention. Therefore, the Examiner does not find this argument to be persuasive.

29. In response to Applicants' argument (8), it should first be noted that the Examiner has not relied upon the use of "education" for teaching any sort of payment mechanism. However, it should also be noted that in claim 1, for example, modification need not be made through any payment mechanism. Instead, all that is required is some sort of modifying of management

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behavior of the at least one physician for the intended outcome of substantially reducing the risk of not receiving the reimbursement amount. It is respectfully submitted that the teachings of Snail, relied upon by the Examiner teach this very broad limitation. Furthermore it should be noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

30. In response to Applicants' argument (9), it is respectfully submitted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the Examiner never relied upon the teachings of Leet to disclose gather data regarding physicians. Rather, as indicated above, Leet has primarily been used, in rejecting the independent claims, to teach gathering data in a tangible computer medium. However, it has also been noted that Leet teaches gathering data regarding medical cost information in a tangible computer medium. Since it appears that Applicants' overlooked the Examiner citation to a portion of Leet in support of this contention, attention is directed to column 15, lines 11-28.

31. In response to Applicants' argument (10), it is noted again that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is respectfully submitted that, similar to above, Applicants' have not considered the combination of references as applied to the claims, along with the portions of the references cited by the Examiner in rejecting the claims. Therefore, the Examiner respectfully maintains that, given the broadest reasonable

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interpretation to one of ordinary skill in the art, the teachings of Snail and Leet, along with the knowledge generally available to one of ordinary skill in the art, teach these limitations.

32. In addition, since Applicants' have not expressly traversed the taking of official notice, these well known teachings are taken to be admitted prior art (see MPEP 2144.03).

Conclusion

33. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

34. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

1/8/07



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